

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Evaluation of cardioprotective effects of “N-acetylcysteine” to cardioplegia and “glucose-insulin-potassium” during coronary artery bypass grafting in patient candidate for CABG

#### Protocol summary

##### Summary

In a double-blind randomized clinical trial, 60 elective CABG patients with EF < 50% will be evaluated. The patients will be numbered according to their reference to the Heart Center of Mazandaran (Iran) and their arrangements in the operation list. They will be randomly allocated to 2 groups of 30 by a computer program to receive either GIK (group G) or NAC (group N). In group G, 10 cc/h of GIK solution will be infused constantly during the surgery. Group N will be injected with a cardioplegic solution containing 200 mg NAC. Normal saline will be used as placebo in both groups (injected in group G and infused constantly in group N) to prevent the surgical team from identifying the drugs. A cardiopulmonary bypass pump will be used for all cases in both groups. Subjects will be excluded in case of requiring intra-aortic balloon pump during the operation, prolonged cross-clamp period of 1.5 hours or more, and sensitivity to NAC. EF, Frequency of arrhythmia, need for inotropic drugs during and after the operation, need for shock and pacemaker, commencement of normal heart rhythm, postoperative levels of cardiac enzymes, ECG changes, central venous pressure (CVP), and duration of hospital and intensive care unit (ICU) stay will be also recorded and compared between the 2 groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211062883N3**  
Registration date: **2012-11-30, 1391/09/10**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-11-30, 1391/09/10

##### Registrant information

###### Name

Mohammadreza Habibi

###### Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1222 3023

###### Email address

mhabibi@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mazandaran University of Medical Sciences and Health Services Deputy of Research

##### Expected recruitment start date

2011-03-20, 1389/12/29

##### Expected recruitment end date

2011-09-21, 1390/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of cardioprotective effects of “N-acetylcysteine” to cardioplegia and “glucose-insulin-potassium” during coronary artery bypass grafting in patient candidate for CABG

##### Public title

Protecting effect of N-acetylcysteine on myocardium during

CABG

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: patients who candidate for CABG with EF below 50% at Mazandaran Heart Center  
Exclusion criteria: Valvular heart diseases; renal failure; liver disease; cross clamp time more than 1:30 min & use of intraaortic balloon pump

**Age**  
From **35 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Mazandaran University of Medical Sciences

**Street address**  
Serah Jouibar, Valiasr Ave.

**City**  
Sari

**Postal code**

**Approval date**  
2011-01-19, 1389/10/29

**Ethics committee reference number**  
89128

## Health conditions studied

### 1

**Description of health condition studied**  
Atherosclerotic cardiovascular disease

**ICD-10 code**  
I25.0

**ICD-10 code description**

Atherosclerotic cardiovascular disease

## Primary outcomes

### 1

**Description**  
ejection fraction of LV

**Timepoint**  
before operation & 5 day after operation

**Method of measurement**  
echocardiograph

## Secondary outcomes

### 1

**Description**  
arrhythmia

**Timepoint**  
during operation & ICU stay

**Method of measurement**  
monitor

## Intervention groups

### 1

**Description**  
Control group: infusion of GIK during operation

**Category**  
Treatment - Drugs

### 2

**Description**  
Intervention group: injection of N Acetylcysteine with cardiopelagic solution

**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**  
Fatemehzahra Hospital

**Full name of responsible person**  
Dr. Mohammadreza Habibi

**Street address**  
Artesh Blv.

**City**  
Sari

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**

Mazandaran University of Medical Sciences and Health Services

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

Deputy of Research, Moalem sq

**City**

Sari

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran University of Medical Sciences and Health Services

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Habibi

**Position**

Assistant Professor; Fellowship of Cadiac Anesthesia

**Other areas of specialty/work**

**Street address**

Mazandaran Heart Center; fattermeh alzahra Hos. Sari

**City**

Sari

**Postal code**

**Phone**

+98 15 1222 3023

**Fax**

**Email**

mohammadreza.habibi@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Habibi

**Position**

Assistant Professor; Fellowship of Cadiac Anesthesia

**Other areas of specialty/work**

**Street address**

Mazandaran Heart Center; fattermeh alzahra Hos.

**City**

Sari

**Postal code**

**Phone**

+98 15 1222 3023

**Fax**

**Email**

mohammadreza.habibi@gmail.com

**Web page address**

www.mazums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Habibi

**Position**

Assistant Professor; Fellowship of Cadiac Anesthesia

**Other areas of specialty/work**

**Street address**

Mazandaran Heart Center; fattermeh alzahra Hos.

**City**

Sari

**Postal code**

**Phone**

+98 15 1222 3023

**Fax**

+98 15 1222 4002

**Email**

mohammareza.habibi@gmail.com

**Web page address**

www.mazums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*